DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 1, 2014

BK Meditech Company, Limited
% Elaine Duncan, M.S.M.E., RAC
Paladin Medical, Incorporated
P.O. Box 560
Stillwater, Minnesota 55082

Re: K140577
Trade/Device Name: INNESIS PEEK TL CAGE
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 28, 2014
Received: August 29, 2014

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140577

Device Name
INNESIS PEEK TL CAGE

Indications for Use *(Describe)*
The INNESIS PEEK TL Cage is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at one level or two continuous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitted on behalf of:

Company Name:	**BK Meditech Co, Ltd**
Address:	**58, Eunhaengnamu-ro** **Hwasung-Si, Kyunggi-Do** **Republic of Korea 445-931**
Telephone:	**82-31-352-9135**
Fax:	**82-31-352-9134**
by:	**Elaine Duncan, M.S.M.E., RAC** **President, Paladin Medical, Inc.** **PO Box 560** **Stillwater, MN 55082**
Telephone:	**715-549-6035**
Fax:	**715-549-5380**

CONTACT PERSON:	**Elaine Duncan**
DATE PREPARED:	**July 21, 2014**
TRADE NAME:	**INNESIS PEEK TL CAGE**
COMMON NAME:	**Intervertebral body fusion device**
DEVICE CLASSIFICATION:	**Class II**
CLASSIFICATION NAME:	**Orthosis, Intervertebral body fusion device, lumbar**
REGULATION:	**888.3080**
PRODUCT CODE:	**MAX**

INDICATIONS FOR USE:

The INNESIS PEEK TL Cage is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at one level or two continuous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

DESCRIPTION of the DEVICE:

The INNESIS PEEK TL Cage was developed as an implant for the posterior stabilization of the lumbar spinal column using a Transforaminal Lumbar Interbody Fusion (T-LIF) technique. The INNESIS PEEK TL Cages are offered in a variety of heights, footprints and curved shapes. The device has ridges on both its inferior and superior surfaces, and two large graft windows which help facilitate bony integration. The device includes marker (pin) for radiological evaluation of the position and orientation of the radiolucent PEEK Cage. The INNESIS PEEK TL Cage components are manufactured from

Polyetheretherketone (VESTAKEEP® I4 R, ASTM F2026). They contain marker made of

510(k) Summary-Continued

medical grade titanium alloy (Ti6Al4V-ELI, ASTM F136). The INNESIS PEEK TL Cage and instrumentation set is sold non-sterile.

SUBSTANTIALLY EQUIVALENT TO:

The subject and predicate devices are substantially equivalent in the areas of materials, design, indications for use and operational principles. Based on the comparison between the subject and predicate devices and testing to standard requirements, BK MEDITECH Co., Ltd. believes that the INNESIS PEEK TL Cages are substantially equivalent to the predicate devices listed below:

510(k)	***Tradename***	***Manufacturer***
K120464-PRIMARY PREDICATE	INNESIS PEEK CAGE	BK MEDITECH Co, Ltd.
K100089-Reference predicate various physical features	SYNTHES T-PAL SPACER	SYNTHES SPINE
K123388-Reference predicate-material	"K7c"	K7, LLC
K100042-Reference predicate-mechanical data	Kyphos Interbody Fusion System	Difusion Technologies

SUMMARY of TESTING per GUIDANCE:

Testing results are for the following:

- Static and dynamic axial compression test, conducted in accordance with ASTM F2077-11
- Static compression shear test, conducted in accordance with ASTM F2077-11
- Static and dynamic torsion test, conducted in accordance with ASTM F2077-11
- Static subsidence test, conducted in accordance with ASTM F2267-04
- Expulsion test, conducted in accordance with ASTM Draft Standard F04.25.02.02.

The material of the INNESIS PEEK TL Cage (permanent implant- long term) is PEEK (Polyetheretherketone, ASTM F2026) and Titanium Alloy (Ti6Al4V-ELI, ASTM F136) are known biocompatible materials. These materials are recognized as suitable biomaterials, have been evaluated to ISO 10993 requirements, and predicate devices have previously been cleared by FDA for this same intended use. The cleaning process to remove manufacturing materials and solution residues has been validated.

Conclusions:

The subject and predicate device(s) share the same intended use, primary implant design and equivalent material of manufacture. Tests performed according to ASTM F2077/ F2267 indicate that The INNESIS PEEK TL Cage meet required mechanical strengths. Some of the predicate devices have a different geometry than The INNESIS PEEK TL Cage. But the non-clinical mechanical test results demonstrate that any minor differences do not impact performance as compared to the predicates and demonstrate that The INNESIS PEEK TL Cage is substantially equivalent to the predicate device.